

## News release

### Biofrontera Reports First Quarter 2019 Financial Results

**Leverkusen, Germany, May 29, 2019** – Biofrontera AG (NASDAQ: BFRA; Frankfurt Stock Exchange: B8F) (the “Company”), an international biopharmaceutical company, today reported its financial results for the first quarter ended March 31, 2019 and provided an update on recent operational and clinical developments.

#### Q1 2019 Financial Highlights:

- Total revenue increased 46% to EUR 6.8 million in Q1 2019 compared to EUR 4.7 million in Q1 2018;
- Net loss was EUR 3.0 million or 6 cents per share in Q1 2019 compared to EUR 3.2 million or 8 cents per share in Q1 2018; and
- Cash and cash equivalents were EUR 21.8 million as of March 31, 2019 compared to EUR 19.5 million as of December 31, 2018.

#### Recent Operational and Clinical Development Highlights:

- Acquired Cutanea Life Sciences, Inc. (Cutanea), a specialty pharmaceutical company focused on dermatology, from Maruho Co., Ltd. (Maruho) in March 2019;
- Expanded research agreement with Maruho to further develop the branded generics program as well as signing a letter of intent to expand the indication for Ameluz® with acne and provide Ameluz® distribution rights to Maruho in parts of Asia and Oceania;
- Reported positive Phase III results of Ameluz® / BF-RhodoLED® for the treatment of actinic keratoses (AK) on the extremities and trunk/neck; and
- Received EMA and FDA approval to upscale the batch size for Ameluz® production.

“Overall, 2019 is shaping up to be a very active year for Biofrontera and we are working diligently to ensure that it will be another year of commercial and strategic success. In the first quarter, we increased total revenue by approximately 46%, with the U.S. as our primary growth driver. The

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Supervisory board: Dr. Ulrich Granzer (Chairman) | Jürgen Baumann (Vice-Chairman)  
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increase marks the fourth consecutive quarter-over-quarter revenue growth. The European label for Ameluz® that now includes daylight PDT for the treatment of AK, supported Germany's growth of 72%. We also expect positive progress in our other European markets throughout the remainder of 2019. These strong results represent our ability to continue to execute on our strategic growth initiatives for Ameluz® and we look forward to leveraging an expanded US-commercial portfolio with AKTIPAK® and Xepi™ from our acquisition of Cutanea Life Sciences, Inc.," commented Prof. Dr. Hermann Lübbert.

### Key financial figures for the first quarter 2019:

In EUR thousands, except where noted	3M 2019	3M 2018	Change
Total Revenue	6,808	4,676	46%
Research and development costs	(1,088)	(938)	(16%)
General administrative costs	(1,974)	(1,416)	(39%)
Sales costs	(5,554)	(4,301)	(29%)
Net loss	(2.980)	(3,172)	6%
Earnings per share (in EUR)	(0.06)	(0.08)	25%

### U.S. Commercial Update

In the first quarter 2019, Biofrontera achieved strong revenue in the United States amounting to 5.2 million, representing revenue growth of 52% compared to the first quarter of 2018. This growth was due to sales to our existing PDT customers as well as new customers.

In January 2019, Biofrontera received approval by the U.S. Food and Drug Administration (FDA) to upscale the batch sizes for the production of Ameluz®. This five-fold increase in batch size will ensure a secure and sustainable supply of Ameluz® to meet the growing U.S. demand as well as substantially improve gross margins.

In March 2019, Biofrontera announced that its subsidiary Biofrontera Inc. has acquired all shares in Cutanea Life Sciences, Ltd., a U.S. based, commercial stage specialty pharmaceutical company focused on dermatology. With the acquisition, Biofrontera expands its US-portfolio to include two additional FDA-approved drugs, AKTIPAK® for the treatment of acne and Xepi™ for the treatment

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of impetigo, including those with MRSA infections. Biofrontera will leverage its established sales and marketing infrastructure to market all three products to dermatologists.

### EU Commercial Update

Sales in Germany improved to EUR 1.1 million, representing a 72% increase compared to the first quarter 2018. The increase was a result of the label extension of Ameluz® for daylight-PDT in 2018. Revenue in the rest of Europe was flat year-over-year at EUR 0.6 million, which was primarily due to the elimination of re-imports within the EU.

### Clinical Update

In March 2019, Biofrontera announced positive results from its Phase III trial evaluating the safety and efficacy of conventional PDT with Ameluz® and BF-RhodoLED® for the treatment of AK on the extremities, trunk and neck. The study met its primary regulatory endpoint, which demonstrated a mean lesion clearance rate per patient's side of 86% for Ameluz® compared to 33% for placebo. Additionally, significant superiority of Ameluz® was demonstrated for all secondary endpoints. Excluding mild AKs and only examining moderate AK lesions, the mean lesion clearance rates per patient's side were 84% with Ameluz® compared to 27% with placebo. In patients treated on the extremities, mean lesion clearance rates per patient's side were also 84% with Ameluz® compared to 27% with placebo. Ameluz® also demonstrated a complete clearance rate of 67% of the patients' sides at 12 weeks post the last PDT treatment, compared to only 12% of the placebo-treated sides. Biofrontera will use these results as basis for the filing of the label extension with the European Medicines Agency (EMA) and the FDA planned in the third quarter of 2019.

Biofrontera also signed an agreement to continue its research cooperation with Maruho for the development of branded generics. As part of the agreement, Biofrontera will begin to prepare one of the four active ingredients formulated using Biofrontera's nanoemulsion technology for clinical trials. In addition, Biofrontera and Maruho are currently in negotiations regarding a possible indication expansion of Ameluz® for acne. The parties are also discussing a license for Maruho to commercialize Ameluz® in Asia and Oceania, where acne is an important market. Maruho would initially assume all development costs for the expanded acne indication, part of which may have to be returned if license negotiations are not successful. Biofrontera would be responsible for carrying

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out the clinical studies required for approval in the U.S.

### Full Year 2019 Guidance

The business development in the first quarter of 2019 is in line with the expectations of the management board. Therefore, the management board fully maintains its forecast for fiscal year 2019 published on 29 April 2019. Among other things, the company expects annual sales of around EUR 35-40 million and a result from operating activities of EUR -7 to -9 million.

### Conference Call

Conference calls for shareholders and interested investors will be held on May 29, 2019 at the following times:

In German, at 10:00 am CET (4:00 am ET)  
Dial-in number Germany: +49 69201744220  
Conference code: 87082878#

In English, at 2:00 pm CET (8:00 am ET)  
Dial-in number USA: +1 8774230830  
Dial-in number UK: +44 2030092470  
Conference code: 77726519#

Please dial in 10 minutes ahead of time to ensure a timely start of the conference call.

The Company's quarterly report including financial statements is available at [www.biofrontera.com/en/investors/financial-reports](http://www.biofrontera.com/en/investors/financial-reports).

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**For enquiries, please contact:**

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### **About Biofrontera:**

Biofrontera AG is a biopharmaceutical company specializing in the development and sale of dermatological drugs and medical cosmetics.

The Germany-based company, with almost 200 employees worldwide, develops and markets innovative products for the care, protection and treatment of the skin. The company's lead product is the combination of Ameluz®, a topical prescription drug, and medical device BF-RhodoLED® for the photodynamic therapy of certain superficial skin cancers and their precursors. Ameluz® has been marketed in the EU since 2012 and in the United States since May 2016. In addition, the company markets AKTIPAK®, a prescription medication for the treatment of acne, and Xepi™ for the treatment of impetigo in the United States. In the EU, the company also sells the dermocosmetics series Belixos®, which offers specialized care for damaged or diseased skin.

Biofrontera is the first German founder-led pharmaceutical company to receive a centralized European and a US approval for a drug developed in-house. The Biofrontera Group was founded in 1997 by the current CEO Prof. Dr. Hermann Lübbert and is listed on the Frankfurt Stock Exchange (Prime Standard) and on the US NASDAQ.[www.biofrontera.com](http://www.biofrontera.com).

### **Forward Looking Statements:**

*Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995 regarding the public offering and the intended use of proceeds from the offering. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate" and "intend," among others. Such forward-looking statements are based on the currently held beliefs and assumptions of the management of Biofrontera AG, which are expressed in good faith and, in their opinion, reasonable. Forward-looking statements involve known and unknown risks, uncertainties and other factors, which may cause the actual results, financial condition, performance, or achievements of the Company, or industry results, to differ materially from the results, financial condition, performance or achievements expressed or implied by such forward-looking statements. These risks, uncertainties and other factors are set forth in the Registration Statement on Form F-1 filed with the SEC, including in the section "Risk Factors," and in future reports filed with the SEC. Given these risks, uncertainties and other factors, prospective investors are cautioned not to place undue reliance on these forward-looking statements. The Company does not undertake an obligation to update or revise any forward-looking statement.*

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